

and a remote center over which corrected cardiac pressure data is transferred. Krichen is relied upon as teaching a system of transferring information from an implanted medical device to a remote center.

Krichen is also characterized as disclosing “an IMD having a pressure sensor.” The examiner cites to column 6, lines 17-19. What is described there is an IMD that can operate in a “rate responsive” mode. As described earlier at column 4, lines 8-20, the IMD is shown as having an activity sensor providing an output that varies as a function of a measured parameter related to the patient’s metabolic requirements. The sensor can be an accelerometer or it can be a sensor that measures the rate of change in right ventricular pressure. An increase in pacing rate is linked to an increase in right ventricular pressure rate of change. Krichen is in contrast to the IMD specified in claim 8, which has a hemodynamic monitor providing cardiac pressure data. An activity sensor as described in Krichen does not provide a measurement of cardiac pressure data.

Also, Krichen discloses that only data obtained by a programmer from an IMD is formatted for communication to a remote center. Halperin on the other hand involves not only obtaining data from an IMD but also combining it with an external data source (pressure sensor) for local use in modification of the operating parameters of the IMD. There is no suggestion in Krichen that IMD data combined with an external data source, as present in Halperin, is to be communicated to a remote center.

The controlling statutory provision of 35 USC §103 requires, as noted on page 2 of the office action, that the differences between the subject matter sought to be patented and the prior art are such that the subject matter “*as a whole would have been obvious*” to a person having ordinary skill in the art. The legal standard applied in the rejection however only finds that one of ordinary skill in the art would have found it obvious *to modify* Halperin with the communication system of Krichen. Thus, the rejection applies an incorrect legal standard.

Even if Halperin could be so modified, that finding nevertheless does not meet the requirement that it would have been obvious to make the claimed combination as a *whole*. For such a finding, there must be some suggestion or motivation for combining the references. *Al-Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308 (Fed. Cir. 1999); *In re*

*Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999). Nowhere does the rejection identify any suggestion to combine the references. The rejection only finds that Halperin could be modified to provide information at a remote location. The Federal Circuit in *In re Dembiczak* reversed the Board's decision of obviousness for a failure, as here, to cite specific information in the prior art that would suggest the combination of the prior art references. *Id.* at 1000.


The examiner appears to place reliance on the level of skill in the art as the source of the motivation. As instructed by the Federal Circuit in *AI-SiteCorp. V. VSI Int'l, Inc.*, 174 F.3d 1308 (Fed. Cir. 1999), it is unlikely that the necessary suggestion can be provided by a showing of the level of ordinary skill in the art because to imbue one skilled in the art with the invention is to fall victim to hindsight reconstruction.

Here, because the Halperin and Krichen references concern different types of data, there is a clear inability to cite to any specific information in Krichen that would suggest modifying Halperin in a manner that would allegedly result in the claimed combination. Absent such a suggestion, a decision of obviousness cannot stand as a matter of law and the rejection is in error.

Therefore, applicant submits that pending claims 8-22 are patentable over the cited references, either singly or in combination. Accordingly, applicant requests that a notice of allowance be issued in due course.

Respectfully submitted,

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**Version with Markings to Show Changes Made**

**IN THE SPECIFICATION**

At page 14, substitute the following paragraph.

Reviewing microcontroller 72 in more detail in Figure 7,[.] EPR serial, interface 74 is in operable data communication with microcontroller 72 and EPR connector 80. It should be noted that EPR connector 80 is disposed in slots 54 (See Figure 5A) to engage EPR 24. Microprocessor 81 is connected to telemetry circuit 82 which in turn is connected to antenna 18. Clocks 86 and 88 run various functions of microcontroller 81. Further, internal LED are represented by block 84.

At page 15, substitute the following paragraph.

Functionally, IRM 20 of the present invention could be used as an interface to transfer medical device information via the known wireless communication systems, patient data to remote location for review in chronic monitoring. IRM 20 operates in conjunction with EPR 24. EPR 24 is generally worn by the patient or kept in close proximity to monitor [environment of biometric] the barometric pressure of the environment.

Substitute the following new Abstract:

**ABSTRACT OF THE INVENTION**

An information remote monitor (IRM) is implemented to collect medical device data locally in a patient's home for transmission to a remote location. Specifically, the IRM integrates data from an external pressure reference (EPR) and an implanted medical device (IMD), preferably the Chronicle™, for remote transmission to a server or a clinical center for follow-up, monitoring and evaluation. The IRM utilizes wireless telemetry to downlink to the IMD and directly engages the EPR to download barometric pressure data to correct cardiac pressure readings from the Chronicle™ or IMD. The IRM may be connected serially to a PC and the PC may control the functions of the IRM. In the alternate, the PC may be used to transfer data from the IRM, through a Web-enabled network system, to a server or a remote location. The IRM utilizes an

integral modem to dial a server and transfer patient data via FTP, PPP and TC/PIP protocols. The IRM includes ergonomic shapes and features adapted for home use including a highly simplified and illustrative user interface that enables the patient to easily operate the device to successfully transfer medical data as needed.